

REMARKS

Claims 1-2 have been rewritten to more definitely set forth the invention and obviate the rejections. Support for the amendments of claims 1 and 2 can be found in the Specification in paragraph [0023], bridging pages 11 and 12, and paragraph [0029], bridging pages 17 and 18. The present amendment is deemed not to introduce new matter. Claims 1 and 2 remain in the application.

Reconsideration is respectfully requested of the rejection of Claim 1 under 35 U.S.C. 103 (a), as being unpatentable over Bowers, et al. in view of Matsuda, et al.

The Bowers, et al. patent, the examiner's primary or principal reference, discloses a treatment process which is preferably conducted in an aqueous medium using a sodium bicarbonate buffer. Further, as described in the instant specification in paragraph [0004] on page 2, Bowers, et al. describes a phosphorylcholine carboxyl derivative that has been turned into an active ester. However, as the Examiner has recognized, Bowers, et al. fails to teach carrying out the method in an organic solvent by means of an after-treatment. Rather, it is respectfully maintained that the examiner's primary reference of Bowers actually tends to teach away from the process called for in amended Claim 1 herein, as teaching the use of an aqueous solution for the after treatment would suggest to one of ordinary skill in the art that such a process would not proceed successfully in an organic solvent.

Further, Bowers, et al. fail to disclose a synthesis method for such a phosphorylcholine carboxyl derivative, as now called for in amended claim 1. Specifically, Bowers, et al. fail to teach or suggest that the carboxyl phosphorylcholine is obtained by the oxidative cleavage of

1- α -glycerophosphorylcholine using periodate and ruthenium trichloride in a water/acetonitrile mixed solvent, as now claimed herein. The present inventors discovered that, unlike using conventional organic synthesis techniques, as one of ordinary skill in the art would do, to produce the phosphorylcholine carboxyl derivative of Bowers, et al., which is cumbersome and very low yield, the synthesis method of the carboxyl phosphorylcholine as now claimed herein proceeds easily at room temperature and requires only a catalytic amount of the ruthenium compound (see Specification, page 18, second paragraph). In response to the Examiner's comments on page 6, paragraph "16.", it is respectfully submitted that such synthesis method is *not* within the ability of one of ordinary skill in the art of organic synthesis, and it is further pointed out that the Examiner has not cited any prior art reference that would teach or suggest same.

As the Examiner has recognized on page 6 of the instant Office Action, the secondary reference of Matsuda, et al., although disclosing after treatment of hydroxyl-functional contact lens materials by esterification with carboxylic acid derivatives in organic and aqueous solvents, fails to teach esterification of the carboxymethyl phosphorylcholine as called for herein. Moreover, Matsuda, et al. fail to teach or suggest the carboxymethyl phosphorylcholine synthesis method as now called for herein in amended claim 1.

With regards to the Examiner's comments in paragraphs "21."-"24.", bridging pages 6 and 7 of the instant Office Action, concerning evidence of unexpected results presented in the specification, it is respectfully submitted that the experimental test results presented in Figure 1 are explained in sufficient detail to enable one of ordinary skill in the art to determine their significance. In particular, as explained in detail in paragraph [0044] on page 26 of the Specification, the "protein level in the solution portion was quantified with the BCA method", and

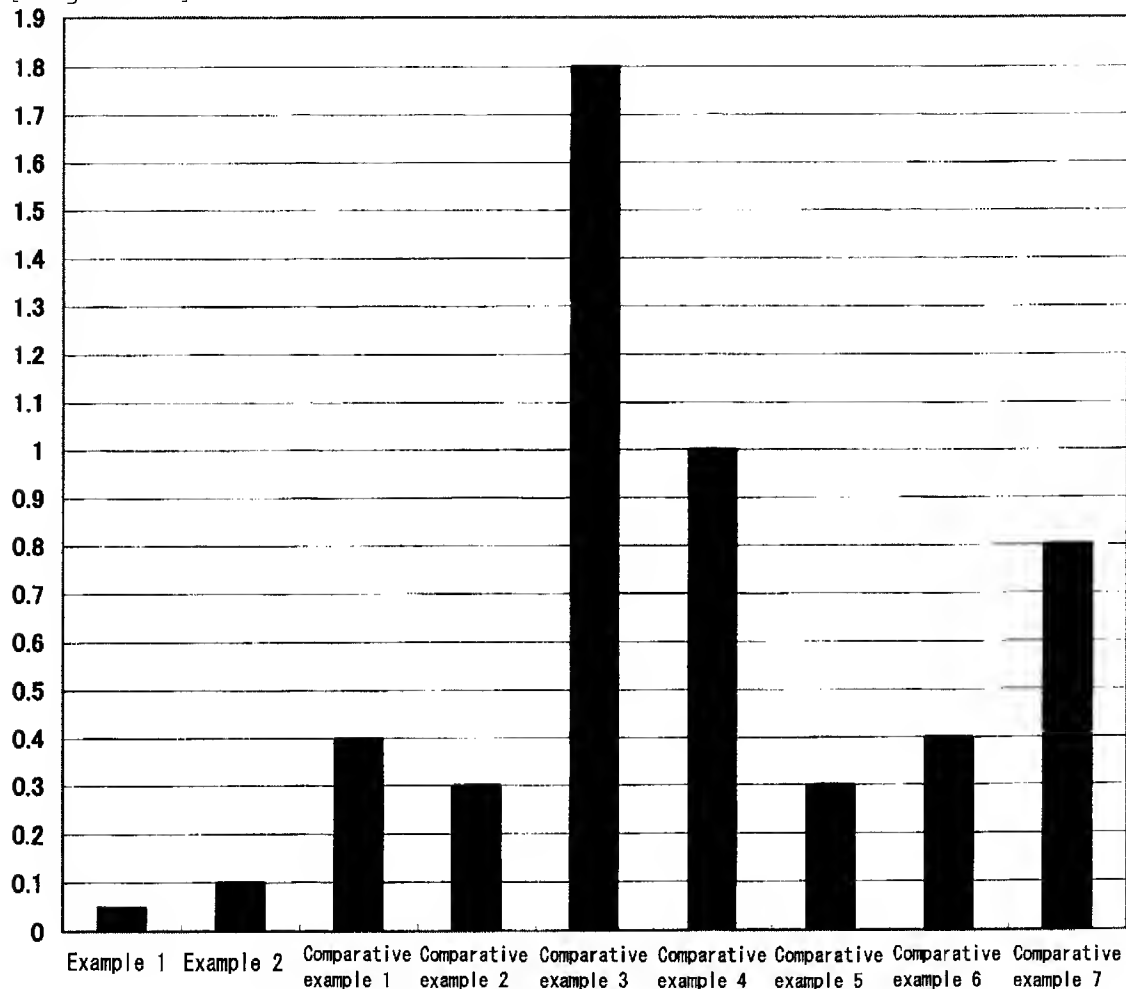
the “protein adsorption level was determined as the reduction in the proteins in the solution portion”. Accordingly, it is clear to the reader that the y-axis denotes adsorbed protein in mg in the contact lens.

Importantly, the experiment disclosed in the instant Specification was conducted in a protein solution of much higher concentration than in Bowers, et al. (mg order vs. μ g order, respectively). Therefore, it is believed that the test conditions presented herein are much more rigorous than those described in Bowers, et al. Further, in view of the fact that the y-axis denotes adsorbed protein in mg, the contact lens of Example 1, is illustrated in Figure 1, adsorbed only 0.05 mg of protein, which is a 97% reduction in protein adsorption versus the untreated commercial product described in comparative example 3 (product name: 1-day Acuvue[®] from Johnson & Johnson, which absorbed 1.8 mg of protein). Clearly, this is an impressive reduction in protein adsorption that, as now claimed herein, is achieved via a carboxymethyl phosphorylcholine synthesized according to a more highly efficient and cost effective process than is conventionally known and utilized.

Further, contrary to the Examiner’s assertions, it is respectfully submitted that the test results shown in Figure 1, as shown below, which clearly show the unexpectedly low amount of protein adsorption by contact lenses manufactured according to the presently claimed method (Examples 1 and 2), versus contact lenses treated according to conventional methods (Comparative Examples 1-7), are *not expected* in view of Bowers’ et al. Although Bowers, et al. in Example 5, purport to achieve a 96% reduction in protein adsorption compared to an untreated lens, the present inventors attempted to replicate such a contact lens, but following the production steps outlined by Bowers, et al., such a contact lens was not producible. Accordingly, it is believed

that Example 5 of Bowers, et al., as relied upon by the Examiner, is inoperable.

[Figure 1]



Moreover, unlike the present invention, Bowers, et al. discloses only 1 tested composition that achieves this alleged result. Thus, it is believed that the Examiner is not warranted in relying upon Example 5 of Bowers, et al. to show a contact lens exhibiting a high degree of protein adsorption reduction. Further, it is respectfully maintained that the test results presented in the Specification demonstrate unexpected results, which according to the previously cited legal authorities, and

contrary to the Examiner's position stated in the instant Office Action, are relevant to the issue of obviousness and must be considered by the Examiner herein.

It is strongly urged that Bowers describes a reduction in protein adsorption by chemically bonding a low molecular weight phosphorylcholine carboxyl compound onto the contact lens surface. That is, formula (V) in column 9, and SCHEME 6 in column 12, in Bowers, et al. describe a chemical structure formula of a phosphorylcholine carboxyl derivative that has been turned into an active ester. However, no description of the synthesis method or Examples is given and therefore this experiment cannot be reproduced; it cannot be called a disclosure of an invention. If said compound, a phosphorylcholine carboxyl derivative having the structure described, were to be synthesized based on ordinary organic chemistry commonsense, the method would be very cumbersome and the yield would be low, indicating very little practical use.

Example 5 in the column 17 describes a method of introducing phosphorylcholine groups onto the surface of a contact lens composed of a 4-hydroxyethyl methacrylate copolymer by treating glycerophosphorylcholine with 1,1'-carbonyldiimidazole. However, the described target phosphorylcholine-treated contact lens could not be obtained as a result of an attempt to duplicate the Example 5 described above. The data showing a 96% reduction in protein deposition of the Example 5 cannot be trusted to an ordinary level of skill in the art of organic synthesis. Therefore, the primary reference of Bowers, et al. is not reliable, and should thus not be cited as the primary reference to reject the present invention.

In view of the amendments to claim 1 herein, as well as the deficiencies of Bowers, et al. and Matsuda, et al., and the legal authorities previously cited herein, it is respectfully submitted that the cited combination of references fails to render unpatentably obvious claim 1 as now

amended herein. Further, it is respectfully maintained that the instant rejection is based solely on hindsight, and fails as a matter of law when the unexpected results are properly taken into consideration. Thus, it is believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Bowers, et al. in view of Matsuda, et al., and further in view of Valint, Jr., et al.

The deficiencies of Bowers and Matsuda, et al. are discussed above.

To cure the deficiencies of the examiner's primary and secondary references, the examiner again relies upon Valint, Jr., et al. which is concerned with surface treatment of a silicone hydrogel contact lens. However, Valint, Jr., et al. neither discloses an after-treatment of a contact lens material with the phosphorylcholine group-containing chemical compound as required by amended Claim 2 herein, nor discloses or suggests the synthesis method of the carboxymethyl phosphorylcholine as now called for herein. Rather, those teachings or suggestions come only from the present invention, and constitute important elements or aspects thereof.

Accordingly, Valint, et al. fails to cure the deficiencies of Bowers, et al. and Matsuda, et al. as discussed above, and thus it is believed that the cited combination of references fails to render unpatentably obvious the method called for in now amended claim 1. Consequently, it is urged that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the

event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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